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Research Article

Evar Under IVUS Guidance: Zero Contrast and Low Radiation Dose

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Abstract

Purpose: Report a prospective single-centre experience using intravascular ultrasound-IVUS to perform endovascular abdominal aortic repair-EVAR avoiding the use of contrast media compared to an historical group of traditional EVAR procedure

Materials and Methods: Thirty-five consecutive patients with an infrarenal abdominal aortic aneurysm-AAA underwent EVAR under fluoroscopy and IVUS guidance. Results were retrospectively compared with a historical group of 35 consecutive patients who underwent standard EVAR. All patients achieved a minimum follow-up of 12 months.

Results: Technical success was achieved in all cases. Mean radiation dose (700 mGy vs 1.200 mGy), mean fluoroscopy time (18.5 min vs 30 min; $p<0.05$) were lower using IVUS. No contrast media was utilized in the IVUS group compared with a mean of 125ml in the control group. Mean procedure time was comparable (57.9 minutes vs control group 49.3 minutes; $p=0.01$). No type I/III endoleaks were detected in either group. Type II endoleaks were observed in 2 (9.1%) patients at 1-day CEUS in the study group, both sealed spontaneously within 6 months, and in 3 cases (8.6 %) of the control group. No deaths and no IVUS-related complications were reported.

Conclusion: IVUS allows accurate and safe endograft deployment avoiding the use of contrast media and reducing the total radiation dose.

Keywords: Abdominal Aortic Aneurysm; Intravascular Ultrasound Imaging; Angiography; Computed Tomography Angiography; Endovascular Aortic Repair

Abbreviations: AAA: Abdominal Aortic Aneurysm; CEUS: Contrast-Enhanced Ultrasound; CIN: Contrast Induced Nephropathy; CKI: Chronic Kidney Insufficiency; eGFR: Estimated Glomerular Filtration Rate; EL: ENDOLEAKS; EVAR: Endovascular Aortic Repair; IVUS: Intravascular Ultrasound; IIA: Internal Iliac Artery

Introduction

Due to recent technical advancements, an increasing number of patients with complex aortic anatomy and multiple comorbidi ties (e.g., tortuous anatomy and chronic renal failure) can be successfully treated with endovascular techniques [1]. Endovascular aortic aneurysm repair (EVAR) is currently performed worldwide using contrast media injection and fluoroscopic guidance. However, renal impairment and allergy to iodinated contrast media are significant contraindications to EVAR. It is estimated that up to 30% of patients undergoing elective EVAR suffer from pre-existing chronic kidney insufficiency (CKI) [2]. Notably, low estimated glomerular filtration rate (eGFR <60 ml/min) may significantly expose the patient to a higher risk of contrast induced nephropathy (CIN) and need for dialysis after EVAR [3,4]. Intravascular ultrasound (IVUS) was introduced over two decades ago as a primary investigative tool and as an adjunct to angiography for the diagnosis and treatment of cardiovascular disease [5]. Due to recent technical improvements, which have led to higher catheter probe resolution, IVUS can be considered not only for the characterization of vessel anatomy, plaque morphology and degree of stenosis, but also as a valid tool for precise evaluation of large calibre vessel diameter as well as procedural guidance [6-8]. However, to date, the literature describing the advantage of the use of IVUS during EVAR procedures is sparse [9,11-14]. The aim of this study is to report our experience and to describe the technique of EVAR performed only with IVUS and fluoroscopic guidance, without the use of iodinated contrast media. A comparison with a historical cohort of standard EVAR procedures was also performed in order to better evaluate the advantages of this technique.

Materials and Methods

This is a prospective, single centre, investigator-initiated study designed to evaluate the efficacy and safety of EVAR performed under IVUS and fluoroscopic guidance without the use of contrast media. The treatment arm included 35 consecutive eligible patients who were enrolled from March to October 2019. An historical control group of patients were identified retrospectively from a registry who underwent standard infrarenal EVAR repair with fluoroscopic guidance and contrast media injection consecutively between July 2018 and February 2019. The registry included those patients who were treated by the same group of physicians in the same hospital. All patients were made aware of the specific technical aspects of this procedure and their informed consent was obtained. The study followed the principles of the Declaration of Helsinki and was approved by the Institutional review board and the local Ethics Committee. The study was not subject to registration at a public trial database because of its observational character.

Patient Work-up and Follow-up

Patients in both groups underwent a pre-treatment CT-angiography (CTA) of the abdominal aorta and iliac-femoral axis to evaluate the morphology and calibre of the aneurysm. Intravenous hydration with normal saline (0.9%) was administered during CTA in patients with CKD, in accordance with the European Society of Urogenital Radiology (ESUR) guidelines [3]. In the study group, proximal neck morphology was defined based on the pre-treatment CTA. All procedures were performed in a dedicated angio-suite with a state-of-the-art angiographic unit (Artis Zee – Siemens-Erlangen-Germany) by the same operator with 20 years of experience in EVAR and endovascular procedures. In both groups, EVAR were performed using different commercially available stent-grafts that were selected based on aortic morphology and anatomical characteristics. All devices used during the EVAR procedures were implanted according to the indication for use.

Procedural characteristics, including time of the procedure (skin to skin), amount of iodinated contrast media, number of angiographic series, fluoroscopy time, and radiation dose were assessed in each group. The occupational radiation dose (estimated effective dose, “E”, measured in millisieverts, mSV) was measured with commercially available personal dosimeters. “E” was reported for the first and the second operators. Dose to patient was extrapolated from the final radiation report of procedures and was measured in mGy. Technical success, defined as correct deployment of the aortic endograft with patent renal and internal iliac arteries with complete exclusion of the aneurysmal sac, was also evaluated. All patients included in the study were followed up through 12 months. Postoperative outcomes included peri- and postprocedural complications, the presence of endoleak, and mortality. All patients underwent contrast-enhanced ultrasound (CEUS – Sonovue, Bracco, Milan, Italy) to exclude the presence of Endo leak (EL) the day after the procedure, at 6 and 12 months. If the CEUS indicated suspicious findings, including Endo leak, a CTA was performed.

Control group

All patients in the control group underwent EVAR using commercially available devices. Procedures were performed in a standard fashion under fluoroscopic guidance with contrast media injection.

Treatment group with IVUS

Patients in the treatment group followed similar IVUS technique during the procedure. An 8.2 Fr IVUS catheter (PV 035 – Philips Volcano, Zaventem, Belgium) was inserted via a 9 Fr introducer on a 0.035” standard angled hydrophilic guidewire (Terumo, Tokyo, Japan) through a common femoral artery access site and advanced up to the supra-renal aorta, above the celiac trunk. Once the catheter was orientated with the celiac trunk at 12 o’clock, a manual pull-back was performed to localize the superior mesenteric artery (SMA) and the origin of the renal arteries (Figure 1).

Then, the following assessments were made at the level of the proximal neck: diameter/length measurement, morphology, and presence of calcium or thrombus. Next, the catheter was partially withdrawn to complete the morphological evaluation of the aorta, aneurysm sac, and the iliac arteries, to visualize the origin of the ipsilateral internal iliac artery (IIA). The IVUS catheter was then inserted in the contralateral femoral access site to evaluate the ilio-femoral axis (diameter, morphology, and origin of the IIA). Moreover, the centimetre markers on the IVUS catheter (1 cm apart) were used to evaluate relevant distances (neck length, aneurysm length, renal artery to internal iliac artery length, etc). The outcomes of the IVUS evaluation were compared to the pre-treatment analysis conducted with CTA in order to confirm the procedure strategy and the endograft selection. With the IVUS catheter in place at the level of the renal arteries, the stent-graft main body was introduced from the contralateral femoral access site and advanced under fluoroscopic guidance. Endograft insertion was performed via common femoral percutaneous access in 28 cases, using a pre-implanted closure device (Prostar XL 10 – Abbott Vascular, Abbott Park, IL). The remaining 7 cases required a bilateral surgical cut-down due to adverse characteristics of the common femoral artery (severe calcification on the anterior wall, diameter less than 8mm). IVUS was used to confirm correct positioning of the endograft at the level of the proximal neck (Figure 2). At this stage, it was crucial to maintain the catheter position to correctly visualize the lower renal artery. For this reason, two operators are utilized: one for the IVUS catheter and the other operator for the endograft device. The release of the proximal portion of the endograft was monitored by direct IVUS visualization to ensure its proper positioning at the inferior margin of the lower renal artery. For a "live" visualization of this stage, fluoroscopy was also used, in the A-P projection. Once the main body of the endograft was fully released, the IVUS catheter was removed (Table 1).

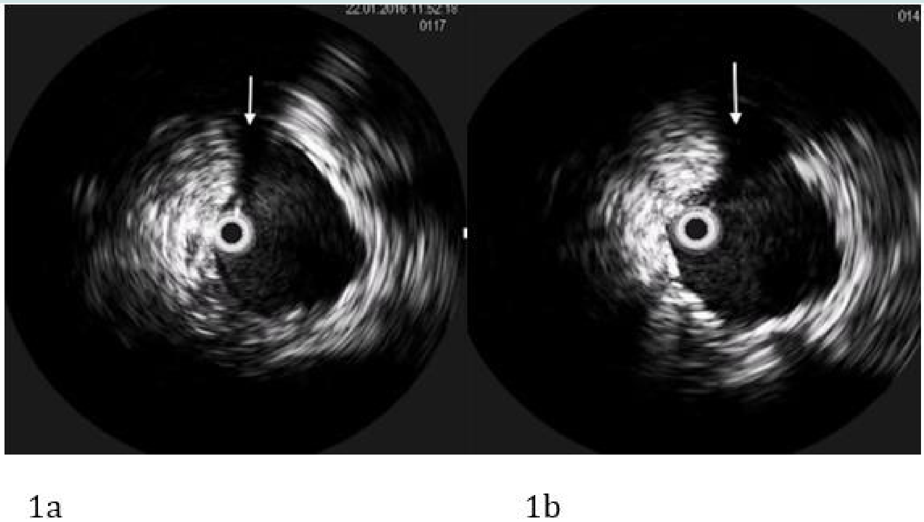

Figure 1: IVUS B-mode images acquired during the initial evaluation of the abdominal aorta. The catheter was advanced above the celiac trunk and then slowly retrieved in order to evaluate the celiac trunk (a, arrow) and the superior mesenteric artery (b, arrow). Notice the catheter orientation equal to the anatomy with the coeliac trunk placed at 12 o'clock.

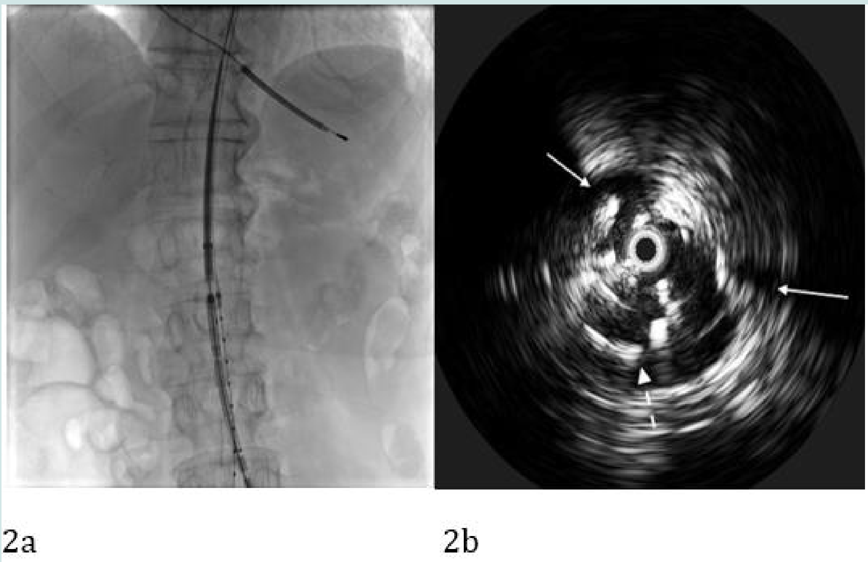

Figure 2: Combined evaluation of fluoroscopic image (a) and IVUS (b) at the level of the proximal neck just before stent-graft deployment. IVUS images allow good visualisation of the renal arteries (arrows) and of the main body of the stent-graft (b, dashed arrow).

Table 1: Demographic and clinical characteristics of the patients included in the study and control group.

Parameter	Study Group	Control Group	Log-rank P value
Number	35	35	1
Male, n (%)	24 (68)	22 (62)	0.6
Age, mean±SD	70.1±5.9	69±5.2	0.7
Smoker, n (%)	19 (54.2)	21 (60)	0.9
Hypertension, n (%)	18 (51.4)	19 (54.2)	0.9
Diabetes, n (%)	17 (48.5)	12 (34.2)	0.9
Hypercholesterolemia, n (%)	10 (28.5)	11 (31.4)	0.8
Previous MI, n (%)	7 (20)	4 (11.4)	0.4
COPD, n (%)	10 (28.5)	9 (25.7)	0.9
Obesity (BMI>30) , n (%)	4 (11.4)	3 (8.5)	0.9
Carotid arterial disease, n (%)	3 (8.5)	5 (14.2)	0.7
Creatinine mean ±SD (mg/dl), n (%)	1.59±0.2	1.1±0.1	0.05
MI: Myocardial Infarction; COPD: Chronic obstructive Pulmonary Disease			

Standard techniques were used for catheterization of the contralateral gate. Once the gate was catheterized, the IVUS catheter was passed through to confirm proper intraluminal location of the wire (Figure 3). Before introduction of the contralateral limb graft, evaluation of the aorta-iliac segment was performed with IVUS to confirm the distance between the gate, the landing zone, and the IIA origin. As it is not possible to simultaneously insert the IVUS catheter and the iliac limb, a Fluoro capture was performed and was used as a reference with the IVUS tip at the level of the IIA origin (Figure 4). The IVUS catheter was then removed, and the iliac limb was inserted under fluoroscopic guidance, and it was subsequently released following the previously acquired image. In the case of a tri-modular device, this step was repeated on the ipsilateral side in order to complete the construction of the endograft. In cases performed with a bi-modular endograft, ipsilateral iliac evaluation (landing zone) was conducted before insertion of the main aorto-iliac body. Post-deployment dilatation of the stent-graft was conducted under fluoroscopy following the standard technique. At the end of the procedure, a final IVUS evaluation was performed to evaluate the endograft diameter, the absence of infolding, and correct wall apposition of the endograft at the level of the proximal and distal landing zones (Figures 5 & 6). Technical steps of the IVUS guided EVAR procedures are summarized in Table 2.

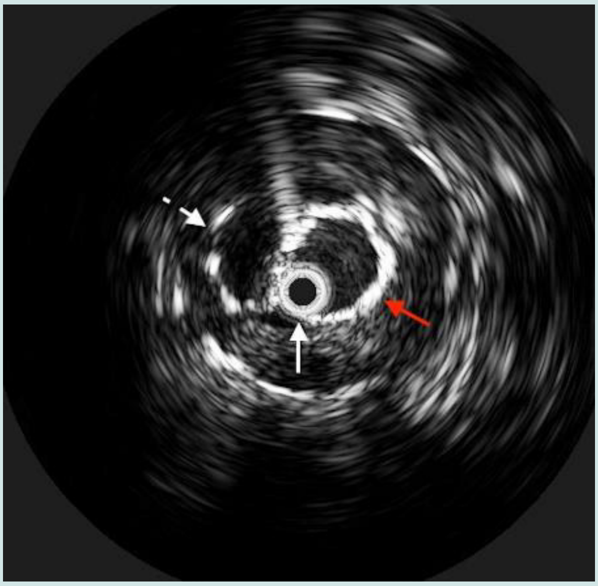

Figure 3: The IVUS catheter (arrow) was used to confirm the correct position inside the contralateral gate (red arrow) after cannulation. Also the ipsilateral limb is clearly visibile (dashed arrow).

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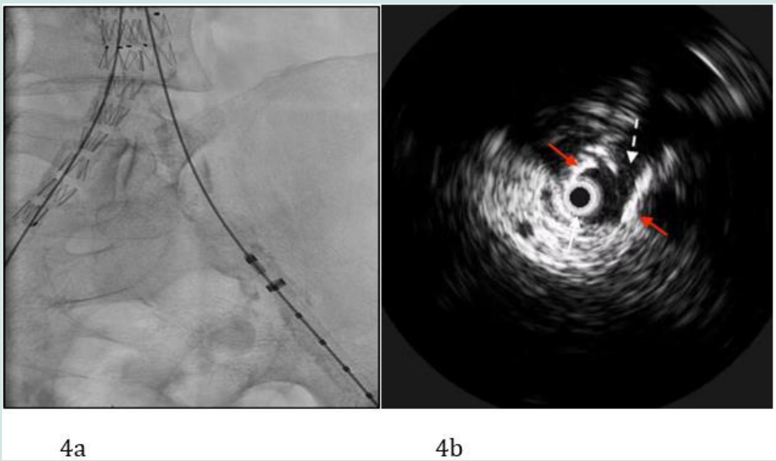

Figure 4: Combined visualization of the origin of the left internal iliac artery performed with fluoroscopy (a) and the IVUS catheter (b, white arrow). Despite the presence of extensive calcified atherosclerotic disease (b, red arrows), the origin of the internal iliac artery is clearly visible (b, dashed arrow).

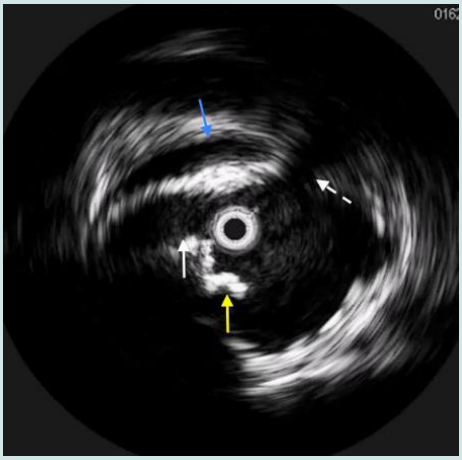

Figure 5: IVUS image at the level of the proximal neck. The IVUS view shows the right renal vein (blue arrow) that is anterior to the right renal artery (white arrow). There is also a bulky calcified plaque (yellow arrow) close to the origin of the right renal artery. The origin of the left renal artery is also visible (dashed arrow).

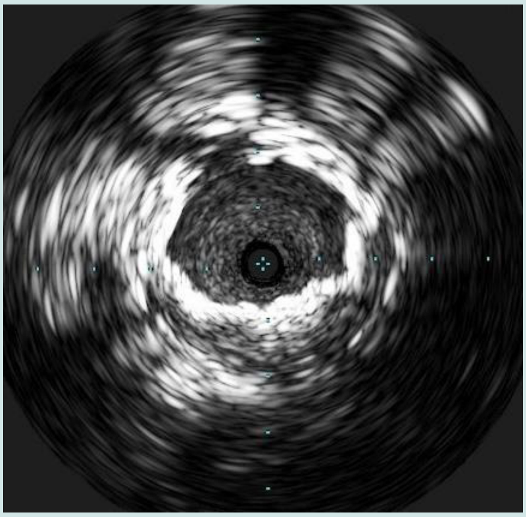

Figure 6: Final IVUS assessment shows correct expansion of the stent-graft body.

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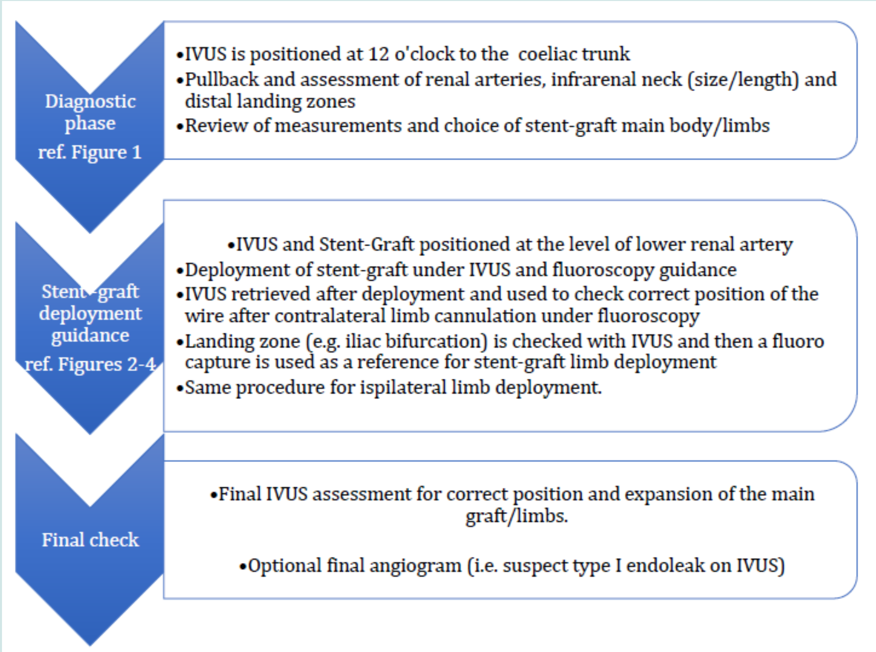

Table 2: Diagram shows the procedural steps of IVUS guided EVAR.

Statistical analysis

Statistical power was calculated at 80% (alpha 0.05) to determine sample size of each group for comparison of procedural features and anatomical measurements. Continuous variables were reported as the mean ±Standard Deviation (SD) or the median and range, as appropriate; differences between the two groups were compared using the student t test. For categorical variable, the absolute and relative proportions were calculated and compared using Fisher's exact test. Significance was assumed at p, 0.05. All analyses were carried out using SPSS for Windows (IBM Corporation, Somers, NY, USA) and Excel for Mac 2008.

Results

Table 1 reports patient demographics and baseline characteristics of both groups. In the treatment group, 68.6% were male (n=24) and had a mean age of 70.1 ± 5.9 years. Patients who underwent EVAR under IVUS guidance had infrarenal AAA with a mean diameter 58.9 mm (range: 46 to 78 mm). Unilateral common iliac artery (CIA) aneurysm was present in 4 cases, while both CIA were involved in one case. The mean age within the control group was 69 ± 5.2 years and 62.8% (n=22) were male. Mean diameter of infrarenal AAA of those who underwent standard EVAR repair was 59.3mm (Range 47 to 76 mm). Two patients in the control group also had a unilateral CIA aneurysm and one patient a bilateral CIA involvement. Different commercially available endografts were used based on aortic morphology and anatomical characteristics.

The following devices were used in the study group and control group: Zenith (Cook Medical) (n=9 vs 6, respectively), Endurant (Medtronic) (n=14 vs 15, respectively), TREO EVAR stent-graft (Bolton Medical) (n=7 vs 5, respectively), and Excluder (Gore) (n=5 vs 9, respectively).

The technical results of all procedures performed in the study and control groups are presented in Table 3. Within the study group, in all cases, the origin of the renal arteries as well as the origin of the other abdominal branches were correctly evaluated by IVUS. A lower accessory renal artery was present in 5 patients (14.2%) and was correctly visualized on IVUS. Technical success was achieved in all patients in both the study and control groups. Mean procedural time in the study group (range 49 to 67 min) was comparable to the control group (range 41 to 60) (57.9 vs. 49.3 minutes, p=0.10). Mean total fluoroscopy time ranged from 12 to 23 minutes in the IVUS group and was significantly shorter in comparison to the control group (17.5 min vs 30 min; p<0.05). Mean radiation dose to patients and to operators was also significantly lower in the IVUS group; in patients, 700 mGy vs 1.200 mGy in the control group; and in operators: 0.021 mSv vs 0.045 mSv in control group, as reported in Table 3. All EVAR procedures in the IVUS group were conducted without injection of contrast media. Contrast media was used for EVAR in the control group (Mean: 125 ml; range 90 ml to 160 ml) and was significantly higher (p<0.05) compared with the treatment group.

Table 3: Anatomical and procedure characteristics in the two groups.

Parameter	Study Group (n. 35)	Control Group (n.35)	P value
AAA Neck shape	Straight (<60°): 12 Conical (<60°): 9 Angled (>60°): 14	Straight (<60°): 11 Conical (<60°): 12 Angled (>60°): 12	0.1
AAA neck size on CTA	25.2±1.4	27.2±1.9	0.2
AAA neck length (mm±SD) on CTA	15.3±3.6	16.3±4.1	0.6
Procedure time (min±SD)	57.9±15	49.3±11	0.1
Fluoroscopy time (min±SD)	18.5±4.5	30±5.5	0.03
DSA acquisition, range (mean)	0	5-8 (6.5)	0.05
Radiation dose to patients,mean mGy±SD	700±60	1200±100	0.01
Radiation dose to operators, mean mSv±SD	0.021±0.01	0.045±0.03	0.04
Contrast media, mean ml±SD	0	115±20	<0.01

No patients died within 30 days postoperatively in either group or no IVUS-related complications were reported in the study group. No type I/III endoleak were detected during follow-up in either group. In the IVUS group, Type II endoleaks were detected in 2 subjects (5.7 %) by CEUS at postoperative day 1. Both were no longer visible at 6-month follow-up and there was no sac enlargement in either case. No stent-graft infoldings were observed at the final IVUS evaluation in all cases. In the control group, type II endoleaks occurred in 3 cases (8.6 %) at postoperative day 1. One sealed spontaneously at 6-month follow-up; in the second patient, percutaneous embolization was required due to progressive sac enlargement; and, in the third patient, no sac enlargement was observed, and no treatment was required. All patients with a type II endoleak underwent a CTA angiography for better evaluation of the sac diameter. No mortality or complications, including endoleak were reported at 1 year follow-up.

Discussion

IVUS is a well-defined imaging method used in different territories. Owing to technological improvements, IVUS-generated images have become increasingly accurate and, as a consequence, IVUS has shifted from a pure imaging modality to a system that is able to guide endovascular procedures. IVUS was used in the aorta for the first time almost 20 years ago [15-24]. Von Segesser [24] reported the use of IVUS for aneurysm repair both in the thoracic and abdominal aorta. He concluded that angiography was no longer necessary in the majority of cases. In 80 patients (12 TAA and 68 AAA), endovascular treatment was carried out with conventional angiography in 31 cases and with IVUS in the other 49. Median radiation exposure was 24 minutes (range 9-65 min) for fluoroscopy/DSA and 8 minutes (range 0-60 min) for IVUS (p<0.05). Moreover, endoleaks were observed more frequently when employing DSA: 26% vs.16% (p<0.05).

Similarly, Pecoraro et al. [14] found promising technical and clinical outcomes of IVUS-guided EVAR, with a freedom from reintervention rate of 85.5% for standard EVAR as well as EVAR+IVUS at 36 months (P = 0.834). However, in the IVUS group, contrast media was still used during the procedure. Not surprisingly, a smaller amount of contrast media utilization was reported when compared to the traditional technique without the use of IVUS (92 [50-125] ml vs 51 [20-68] ml p<0.003). In this study, EVAR was performed entirely without the use of contrast media, offering obvious advantages when compared to the traditional technique used in the control group (0 ml vs. 125±20 ml; p<0.05). This is especially apparent for CKD patients. Up to 30% of patients with AAA suffer from chronic renal insufficiency with high risk to develop contrast-induced nephrotoxicity (CIN) [16]. For this reason, several methods have been studied to reduce or avoid the use of contrast media during EVAR, such as Carbon Dioxide (CO2), duplex-ultrasound as additional guidance, and intraoperative contrast-enhanced ultrasound [17-20]. However, each modality has significant limitations especially when compared with IVUS.

For example, CO2 requires dedicated systems to be injected and specific software to assess the final image that is a summation of single frames. As reported by Chao et al., this tremendously increases the radiation dose [20]. In addition, Lee et al. described a lower sensibility in the visualization of the renal arteries [21]. On the other hand, CO2 angiography has a higher sensitivity for endoleak detection due to the low viscosity of the gas that fills the sac earlier [20,21]. IVUS allows a precise assessment of the aortic lumen in severe tortuosity, thus reducing the need to perform multiple angiographic images in different projections. This results in a lower radiation exposure and shorter fluoroscopy time [7]. In addition, our study showed a significantly reduced radiation dose (-42%) for both patients and operators in the study group [22-24]. This is extremely useful not only for the patients but also for the operators as they are exposed to radiation almost every day. Complications secondary to radiation exposure during endovascular procedures are now well known [25] and should be limited, aiming to use imaging techniques with low or no radiation exposure. Another alternative method to reduce radiation exposure during EVAR is image fusion technology [26,27]. However, this technique presents several limitations. First, it is available only in high-cost hybrid rooms, and therefore only in high-volume centers. Second, it is time-consuming and may be cumbersome to use, and therefore physicians may not use it, especially in cases of simple procedures [26,28].

Utilizing IVUS may require a learning curve, although image interpretation is not extremely complex. The orientation of the IVUS catheter is one of the key elements to performing a correct interpretation of the images. When used in the abdominal aorta to visualize a vessel, it can be difficult, if not impossible, to understand which vessel is being observed. In the same way, it can be challenging to understand the difference between the right and the left renal artery. For this reason, we always start our evaluation from the celiac trunk because it is easy to define since it is the first branch encountered when entering the abdominal aorta from above. Then, the catheter is rotated in order to keep the celiac trunk at 12 o'clock (it can also be at 3, 6, 9 o'clock). When the pull-back of the IVUS catheter is performed, is crucial to not rotate it. Only in this way, the right and left renal arteries can be correctly recognized without any misinterpretation. Visualization of the right renal vein can be also of great help to distinguish the right and left renal arteries as the renal vein is almost always anterior (incidence of retro-aortic left renal vein is 3.2%) (Figure 5). While overall procedure times using IVUS may vary, our study did not find significant difference between the two groups.

Despite the several advantages of using IVUS for EVAR procedures, some limitations must be taken in account. Surely, the learning curve, procedural costs, and adjunctive follow-up techniques (e.g., CEUS at 24 hours) represent the most important ones. However, there are further limitations strictly related to IVUS technology. First, it is not possible to directly evaluate the presence of an endoleak; only a gap between the endograft and the aortic wall at the level of the landing zone can be visualized (as an indirect sign for a type I endoleak). Second, the IVUS catheter does not allow for a "front" view. For this reason, it cannot be used for the catheterization of the contralateral gate that still requires the traditional technique with several projections under fluoroscopy. Finally, "contrast-free EVAR" should be performed by two operators.

Conclusion

IVUS has rapidly developed from a simple diagnostic modality to a guiding tool for a multitude of endovascular interventions. It allows for a significant reduction of radiation exposure as well as complete avoidance of the use of iodinated contrast media. Nonetheless, this technique is not always available, and it is still not widely used due to lack of diagnostic sensitivity necessary for detecting intraoperative endoleaks. However more studies are required to fully validate this technology. We also look forward to future technical improvements (catheter miniaturization, flow evaluation) that can increase the advantages of IVUS guidance.

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